DEPARTMENT OF HEALTH AND HUMAN SERVICES

95059d

Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

November 2, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2005-03

Mr. Richard A. Reid, Owner
Reid's Bus Service
109 E. Street
Creighton, MO 64739

Dear Mr. Reid:

This letter serves as your formal notification that the U.S. Food and Drug Administration (FDA) has classified your bus service support facility, located in Creighton, Missouri, as "Provisional" for interstate carrier use.

On September 23, 2004, a U. S. Food and Drug Administration Investigator conducted an inspection of your facility used as a service area for waste disposal. This inspection revealed significant deviation from the Interstate Conveyance Sanitation regulations, Title 21, Code of Federal Regulations, Part 1250 (21 CFR 1250), issued under the authority of the Public Health Service Act.

During the inspection, the following significant deficiency was noted:

- Failure to have a backflow prevention device installed on the hydrant used to flush and clean out the toilet wastes from buses serviced at your station as required by (21 CFR 1250.75(b)).

The above deficiency was included in the list of Inspectional Observations (FDA Form 483) that was issued to Mr. U. Darrell Reid immediately after the inspection.

The deficiency found at your bus servicing facility may cause contamination of the potable water supply with human sewage and contribute to the spread of communicable disease. This same deficiency has been observed at your facility during prior inspections. Based on the inspectional findings, we are classifying your facility as "Provisional" for interstate carrier use. A "Provisional" classification means that the facility may continue to operate; however,

correction of deficiency must be made by the time the facility is re-inspected. If significant corrections are not made by the time of the next inspection, the facility will be reclassified as "Use Prohibited" for carrier use. A classification of "Use Prohibited" prohibits the use of your facility by interstate conveyances until the deficiency has been corrected and the facility has been re-inspected by FDA.

You should notify this office in writing within fifteen (15) working days of the receipt of this letter of the steps you have taken to address the deficiency and prevent its recurrence. Include copies of any available documentation demonstrating that corrections have already been made.

Your response should be directed to the attention of Joseph G. Kramer, Compliance Officer, U.S. Food and Drug Administration, 11630 West 80th Street, Lenexa, Kansas 66214, phone (913) 752-2719.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District